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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,579	01/25/2001	Hector F. DeLuca	960296.95700	4517

7590 09/09/2004

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,579	DELUCA ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/21/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2004 has been entered.

Claims 1-5, 11-15 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the claim amendments.

Claim Rejections - 35 USC § 102

1. Claims 1-5, 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathieu et al US Patent 5,665,387.

2. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Mathieu teaches methods of treating autoimmune diabetes which is caused by autoimmune destruction of B cells comprising administering tablets of 1α, 25-dihydroxyvitamin D_3 (1,25 $(OH)_2D_3$) to a subject within at similar doses as instantly claimed. (see col 2, lines 1-10; col 10, lines 1-41; claim 4, 12-17). Autoimmune destruction of B cells leads to Type I diabetes. Contrary to applicant's arguments, Mathieu also teaches that his compositions can be orally for treating diabetes. At col 4, line 45 Mathieus states:

Pharmaceutical compositions, comprising vitamin D and/ or its analogue(s) as the active ingredient for preventing primary and secondary diabetes have the form of powders, suspensions, solutions, sprays, emulsions, unguents or creams and can he used for local application, intranasal, rectal, vaginal and also for oral or parenteral (intravenous intradermal, intramuscular, intrathecal etc.) administration. Such compositions can be prepared by combining (i.e. by mixing, dissolving etc.) the active compound(s) in the form of a free acid or salt with pharmaceutically acceptable excipients with neutral character (such as aqueous or non-aquous solvents, stabilizers, emulsifiers, detergents, additives), and further if necessary colouring agents and flavouring agents. The concentration of the active ingredient in a pharmaceutical composition can vary between 0.001% and 100%, depending on the nature of the treatment and the method of administration. The dose of the active ingredient that is administered can further be varied between 0.1 µg and 1 mg per kg body-weight, preferably between 0.1 µg and 100 µg per kg body-weight.

Mathieu further claims:

1. A method for modulating the immune system of a subject comprising administrating an amount in a range of 0.1 ug to 1 mg per kilogram body-weight of said subject of a first compound based on the formula

9. The method according to claim 1 wherein said first compound is administered as a pharmaceutical formulation containing at least one pharmaceutically acceptable excipient and said amount of said first compound.

10. The method according to claim 9 wherein said pharmaceutical formation is selected from the group consisting of powders, suspensions, solutions, emulsions, capsules or tablets for enteral or parenteral administration.

Accordingly, Mathieu is viewed to discloses administration of 1α, 25-dihydroxyvitamin D_3 (1,25 $(OH)_2D_3$) tablets to a subject similar doses as instantly claimed.

Mathieu also discloses modulating the immune system in patients in need of such therapy who have predisposition to develop autoimmune diabetes (abstract, col 2, lines 40-50; 7-8). Such groups of people are construed as predisposed subjects to type I diabetes. (see col 2, lines 45-50). Accordingly, Mathieu describes all elements of claims 1-5.

Since Mathieu modulates development of diabetes I in subjects, the type I diabetes are viewed to be inherently detectable in such patients with autoantibodies to glutamic acid decarboxylase, because such detectability is a function of the disease. Therefore, Mathieu also meets the limitations of claims 11-15.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SHENGJUN WANG
PRIMARY EXAMINER